

**ACETAMINOPHEN 250MG ASPIRIN 250MG CAFFEINE 65MG- acetaminophen 250mg  
aspirin 250mg caffeine 65mg tablet  
CVS Pharmacy**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

**CVS Headache Relief Geltabs  
Acetaminophen 250mg, Aspirin 250mg, Caffeine 65mg**

Acetaminophen 250mg

Aspirin 250mg

Caffeine 65mg

ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow No. 10 lake, ethyl cellulose, FD&C blue No. 1 lake, FD&C red No. 40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, povidone, pregelatinised starch, propylene glycol, shellac glaze, sorbitol sorbitan, stearic acid, talc, titanium dioxide, triacetin.

- Do not use more than directed
- Drink a full glass of water with each dose
- Adults and children 12 years and over: take 2 geltabs every 6 hours; not more than 8 geltabs in 24 hours
- Children under 12 years: ask a doctor

Temporarily relieves minor aches and pains due to:

Headache, a cold, arthritis, muscular aches, toothache, premenstrual and menstrual cramps

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take more than 8 geltabs in 24 hours, which is the maximum daily amount, with other drugs contains acetaminophen, 3 or more alcoholic drinks every day while using this product.

**Stomach bleeding warning:** This contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using product, take more or for a longer time than directed.

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

**Do not use** if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain

reliever/ fever, with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use** if you have liver disease, stomach bleeding warning applies to you, you have a history of stomach problems, such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you are taking a diuretic, you have asthma.

**Ask a doctor or pharmacist before use** if you are taking a prescription drug for diabetes, gout, or arthritis, any other drug, or are under a doctor's care for any serious condition.

**Stop use and ask a doctor** if an allergic reaction occurs. Seek medical help right away. You experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better, ringing in the ears or loss of hearing occurs, painful area is red or swollen, pain gets worse or lasts for more than 10 days, fever gets worse or lasts for more than 3 days, any new symptoms occur. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

**Keep out of reach of children.**

**OVERDOSE WARNING:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

Pain reliever

Pain reliever

Pain reliever aid

- Store at room temperature between 20-25 °C (68-77 °F)
- Avoid excessive heat, cold, and humidity
- Close cap tightly after use
- Read all product information before using. Keep box for important information.



Geltabs

NDC 59779-132-80

**EXTRA  
STRENGTH**

# Headache Relief

**ACETAMINOPHEN  
ASPIRIN (NSAID)  
& CAFFEINE**

**Pain reliever  
Pain reliever aid**



Actual Size

**80 GELTABS**

Compare to the active ingredients in  
Excedrin® Extra Strength†

Compare to the active ingredients in  
Excedrin® Extra Strength†

## Drug Facts

**Active ingredients (in each geltab)**  
Acetaminophen 250 mg  
Aspirin 250 mg (NSAID)  
Caffeine 65 mg  
\*nonsteroidal anti-inflammatory drug

### Uses

Temporarily relieves minor aches and pains due to:  
■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache  
■ menstrual and menstrual cramps

### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash  
If a skin reaction occurs, stop use and seek medical help right away.  
**Allergy alert:** Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 geltabs in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID. NSAIDs may cause stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasional rapid heart beat.

## Other information

■ store at room temperature between 20-25°C (68 to 77°F)  
■ avoid excessive heat, cold and humidity  
■ read all product information before using

**Inactive ingredients:** ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow no. 10 lake, ethyl cellulose, FD&C blue no. 1 lake, FD&C red no. 40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, isopropyl alcohol, isopropyl alcohol-butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polyethylene glycol 600, polyethylene glycol 400, polyethylene glycol 300, purified water, and/or glaze.

## Questions or comments? 1-888-577-8033

THIS PRODUCT DOES NOT REQUIRE A RECIPE. KEEP OUT OF REACH OF CHILDREN. KEEP OUT OF REACH OF CHILDREN.

CVS Quality  
V-57398  
Made in U.S.A.  
CVS.com® 1-800-SHOP CVS  
© 2021 CVS/Pharmacy  
One CVS Drive, Woonsocket, RI 02896  
Distributed by: CVS Pharmacy, Inc.  
Healthcare, distributor of Excedrin®  
Extra Strength.

#695041  
FPO 90%  
UPC# 0504282999220  
X XXXXXX XXXXXX X

Lot No.: CT597913280 REV/06-12/2020

Exp. Date:



Compare to the active ingredients in  
Excedrin® Extra Strength†

Geltabs

NDC 59779-132-80

**EXTRA STRENGTH**

# Headache Relief

**ACETAMINOPHEN, ASPIRIN (NSAID)  
& CAFFEINE**

**Pain reliever, Pain reliever aid**



Actual Size

**80 GELTABS**

## Drug Facts (continued)

**Do not use** ■ if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if** ■ you have liver disease ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma

**Ask a doctor or pharmacist before use if you are taking** ■ a prescription drug for diabetes, gout, or arthritis ■ any other drug, or are under a doctor's care for any serious condition

**Stop use and ask a doctor if** ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ ringing in the ears or loss of hearing occurs ■ pain in the back or swollen ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ any new symptoms occur

These could be signs of a serious condition. ■ if pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**  
**OVERDOSE WARNING:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

■ do not use more than directed ■ drink a full glass of water with each dose ■ adults and children 12 years and over: take 2 geltabs every 6 hours, not more than 8 geltabs in 24 hours ■ children under 12 years: ask a doctor





Compare to the active ingredients in:  
Excedrin® Extra Strength†

Gel tabs

NDC 59779-132-23

EXTRA STRENGTH

# Headache Relief

ACETAMINOPHEN,  
ASPIRIN (NSAID)  
& CAFFEINE

Pain reliever,  
Pain reliever aid

20 GELTABS

Actual Size



## Drug Facts (continued)

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
    - feel faint
    - vomit blood
    - have bloody or black stools
  - have stomach pain that does not get better
  - ringing in the ears or loss of hearing occurs
  - painful area is red or swollen
  - pain gets worse or lasts for more than 10 days
  - fever gets worse or lasts for more than 3 days
  - any new symptoms occur
- These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**  
**OVERDOSE WARNING:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 gel tabs every 6 hours, not more than 8 gel tabs in 24 hours
- children under 12 years: ask a doctor

## Drug Facts (continued)

**3 or more alcoholic drinks every day while using this product**  
**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasional rapid heartbeat.

**Do not use** if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer with any other drug containing acetaminophen, prescription or nonprescription. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if:**

- you have liver disease
- stomach bleeding/warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

**Ask a doctor or pharmacist before use if you are taking:**

- a prescription drug for diabetes, gout, or arthritis

## Drug Facts (continued)

**Other information**

- store at room temperature between 20°-25°C (68° to 77°F)
- avoid excessive heat, cold and humidity
- close cap tightly after use
- read all product information before using. **Keep outer box for full information.**

**Inactive ingredients** ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow no. 10 lake, ethyl cellulose, FD&C blue no. 1 lake, FD&C red no. 40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, isopropyl alcohol, isopropyl alcohol-butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polysorb 85/70/00, povidone K 30, pregelatinized starch, propylene glycol, purified water, shellac glaze, stearic acid, talc, titanium dioxide, triacetin

**Questions or comments?** 1-888-577-8033

## Drug Facts

### Active ingredients (in each gel tab)

Acetaminophen 250 mg  
Aspirin 250 mg (NSAID)\*  
Caffeine 65 mg  
\*nonsteroidal anti-inflammatory drug

### Purposes

Pain reliever  
Pain reliever aid

### Uses

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache

premenstrual & menstrual cramps

### Warnings

**Feet's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's Syndrome, a rare but serious illness.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take more than 8 gel tabs in 24 hours, which is the maximum daily amount. With other drugs containing acetaminophen.

Exp Date: \_\_\_\_\_  
Lot No.: \_\_\_\_\_  
CT5977913223 REV100-11/2020  
†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.  
Distributed by:  
CVS Pharmacy, Inc.  
One CVS Drive  
Woonsocket, RI 02896  
© 2021 CVS/pharmacy  
CVS.com® 1-800-SHOP CVS  
Made in U.A.E.  
V-37388  
#695046  
FPO 80%  
UPC# 050428343654  
X XXXXXX XXXXXX X

7  
[177.8]

7

Adhesive Area  
All else is  
deadened

acetaminophen 250mg aspirin 250mg caffeine 65mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-591
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
STARCH, CORN (UNII: O8232NY3SJ)	
AMMONIA (UNII: 5138Q19F1X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TALC (UNII: 7SEV7J4R1U)	
SHELLAC (UNII: 46N107B71O)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	green (Dark Green - White)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	S77
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-591-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
2	NDC:69842-591-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
3	NDC:69842-591-23	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information			
-----------------------	--	--	--



Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/01/2021	

**Labeler** - CVS Pharmacy (062312574)

Revised: 1/2021

CVS Pharmacy